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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,409

06/17/2005

Reinhold Buck

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22852

7590

02/23/2010

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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,409	Applicant(s) BUCK ET AL.	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/12/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's request for continued examination filed February 12, 2010 is acknowledged. Claims 1-2 have been amended and claims 16-28 and 32 are cancelled. Claims 1-15 and 29-31 are pending and further considered on the merits.

Response to Amendment

In response to applicant's amendment, the examiner maintains and further clarifies the grounds of rejection set forth in the office action dated October 15, 2009.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1, 3-13, and 29** are rejected under 35 U.S.C. 103(a) as obvious over Buck et al., US 4935141 (Buck) in view of Lee et al., US 5571418 (Lee) and evidenced by Gorsuch et al., US 6802820 (Gorsuch).
3. Regarding claims 1-11, 13, and 26-29, Buck discloses an asymmetric hollow fiber membrane (Claim 1) comprising:
 - a. At least one hydrophobic polymer present in an amount of 50-80% by weight, wherein said polymer is polysulfone (Ex. 1-2, 4-5, and Claims 6-7, 9) and has domains present on the membrane surface (implicitly disclosed);
 - b. At least one hydrophilic polymer present in an amount of 20-50% by weight, wherein said hydrophilic polymer is polyvinylpyrrolidone (Ex. 1-2, 4-5, and Claims 6-7, 9) and has domains present on the membrane surface (implicitly disclosed);
 - c. A three layer asymmetric structure (Fig. 1A-B) wherein a separation layer less than 1 μ m thick (col. 3, l. 53-55 and col. 4, l. 8-16) contains pore channels with a pore size of 20-40nm (Claim 2).
4. Buck discloses the membrane allowing passage of molecules having a molecular weight of up to 45kD with a sieving coefficient of 0.1 to 1.0 (implicitly disclosed in col. 3, l. 65 – col. 4, l. 7 and col. 5, l. 46-54) and further discloses proteins having a molecular weight of at least that of albumin are completely rejected from the membrane (col. 5, l.

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46-54). Furthermore, Buck discloses a membrane wherein the sieving coefficient for albumin is about 0.001 (col. 5, l. 52-53).

5. Regarding the limitation of a separation layer having a thickness of less than 0.5 μ m, while Buck discloses a separation layer preferably less than 1 μ m thick, Buck fails to explicitly disclose a membrane having a separation layer less than 0.5 μ m thick. However, at the time of invention it would have been obvious to one skilled in the art to optimize the thickness of said separation layer to include being less than 0.5 μ m thick, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Part II).

6. Buck fails to explicitly disclose a membrane that has a molecular weight exclusion limit of about 200kD with a sieving coefficient of 0.1 in water, nevertheless, Buck discloses a membrane with the same preferred structure as contained in Applicant's claims/specification; therefore, it is inherent that the membrane has such a property, absent evidence to the contrary (MPEP 2112).

7. Furthermore, a sieving coefficient of 0.1 indicates very low permeability of solutes across the membrane, and it would be obvious to a routineer in the art that particles having a molecular weight of 200kD will have very low permeability across a membrane that excludes 68kD proteins (albumin) in light of the teachings disclosed in Buck.

8. Moreover, molecular weight exclusion limits in water are deemed to be result effective variables as evidenced by Gorsuch (fig. 7). Gorsuch provides evidence in fig. 7 that size exclusion limits and sieving coefficients can be easily manipulated based on the test methods used to determine the size exclusion limits and sieving coefficients; and a multitude of possible structural and operational limitations can be envisaged based on these characteristics. Therefore, many hollow fiber membranes would appear to have the desired size exclusion limit and sieving coefficients and the size exclusion limit and sieving coefficient has no limiting effect.

9. Lee discloses hollow fiber membranes having molecular weight exclusion limits of between 100kD and 150kD which is advantageous as a therapeutic regimen for multiple organ failure, sepsis, or systemic inflammatory response syndrome (col. 2, l. 50-61).

10. At the time of invention, it would have been obvious to one skilled in the art to modify the membrane of Buck to include the molecular weight exclusion parameters of Lee, since it has been shown in the prior art to be an effective therapeutic regimen for sepsis, multiple organ failure, and systemic inflammatory response syndrome, and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144, Part II).

11. Regarding claim 12, Buck fails to disclose a membrane that has a sieving coefficient for IL-6 in whole blood between 0.9 and 1.0, nevertheless, Buck discloses a membrane with the same preferred structure as contained in Applicant's claims/specification; therefore, it is inherent that the membrane has such a property, absent evidence to the contrary (MPEP 2112).

12. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Buck in view of Lee as relied upon in the rejection of claim 1 above, and in further view of Deppisch et al., "Blood Material Interactions at the Surfaces of Membranes in Medical Applications" (Deppisch).

13. Buck fails to explicitly disclose the size of hydrophilic domains on the membrane surface are in the range of 20-50nm. However it is well known, as disclosed by Deppisch, that polyvinylpyrrolidone hemodialysis membranes such as those disclosed by Buck have hydrophilic domains in the range of 20-200 nm (Pg. 247, Col. 2, Para. 1) and that hydrophilic domains improve thrombogenicity (Pg. 248, col. 2, l. 1-4). Since, Deppisch recognizes hydrophilic domains as a result effective variable, it would have been obvious to a person having ordinary skill in the art to optimize the size of the domains as it has been held that it is not inventive to discover the optimum ranges by routine experimentation (MPEP 2144.05, Part II).

14. **Claims 14-15 and 30-31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck in view of Lee as relied upon in the rejection of claim 1 above, further evidenced by Kagawa et al., EP 0568045 (Kagawa).

15. Regarding claims 14-15, 30-31, Buck implicitly has an outer layer, different from the finger-like structure and this outer layer is equated with applicant's fourth layer. As evidenced by the similarities between fig. 1B of Buck and fig. 4 of applicant's

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specification, it is presumed that the structure of Buck has the stated properties of an outer surface including a pore size of 0.5 to 3 micron, alternatively it would have been obvious to produce a membrane with a outer layer pore size in the range of 0.5 to 3 micron based on the teachings of Buck which has the same sponge-like and finger-like structure of layers and the same inner layer pore size, as evidenced by Kagawa.

Kagawa discloses that outer surface layer has micropores with a 0.1-0.5 micron average pore diameter (Pg. 10, Lines 44-51).

16. Further, it is either inherent or would have been obvious to produce an outer sponge layer with the property of pore density in the range of 20,000 to 100,000 pores per mm^2 based on the similarity in structure and as evidenced by Kagawa. Kagawa discloses the process conditions can be modified to optimize the outer surface structure using a spinning process whereby hollow fiber membranes having many micropores of relatively large diameter in their outer surface can be readily obtained. Kagawa presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore size and number of pores on the surface with a reasonable expectation of success.

17. Alternatively, although Buck does not appear to expressly disclose that this outer layer is the fourth layer, it would have been obvious to one having ordinary skill in the art to include a fourth layer as it has been held that mere duplication of parts has no patentable significance (MPEP 2144.04, Part VI). Including four layers in a hollow fiber membrane is well-known, as evidenced by Gorsuch. Gorsuch discloses four zones in a hollow fiber membrane (Fig. 1). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

18. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/

Primary Examiner, Art Unit 1797

/DRB/

Dirk R. Bass